Pharmacy Policy

Xiaflex

Policy Number: 9.911
Version Number: 2.0
Version Effective Date: 3/1/2022

Product Applicability	☐ **All Plan⁺ Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☐ New Hampshire Medicaid	☒ MassHealth - MCO ☒ MassHealth - ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Xiaflex (collagenase clostridium histolyticum)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None
Required Medical Information	1. A diagnosis of Dupuytren's contracture with palpable cords; AND a. Flexion contracture ≥ 20 degrees in metacarpophalangeal joint (MP) or proximal interphalangeal joint (PIP) of affected finger; AND b. Must not have had surgery on the primary joint within the past 90 days; OR 2. A diagnosis of moderate to severe Peyronie's Disease (PD); AND a. A palpable plaque; AND

⁺ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	b. Curvature of greater than 30 degrees; AND c. Symptoms have persisted for greater than 12 months
Age Restriction	18 years of age and older
Prescriber Restriction	Peyronie's Disease: Prescribed by or in consultation with a Urologist Dupuytren's contracture: Prescribed by or in consultation with a provider experienced in the treatment of DC
Coverage Duration	Dupuytren's contracture: 3 months Peyronie's disease: 6 months
Other criteria	None

Applicable Coding

HCPCS Code	Description
J0775	Collagenase clostridum histolyticum 0.01mg

Clinical Background Information and References

1. Product Information. Xiaflex™ (collagenase clostridium histolyticum). Auxilium Pharmaceuticals, Inc. Malvern, PA 19355. July 2015.
2. Eric Brodsky, MD. FDA Perspective- Xiaflex™ for Advanced Dupuytren's Disease. Available at http://www.dupuytrenfoundation.org/DupPDFs/2009_FDA.pdf Accessed April 14, 2010
3. Rohit A and Blazar PE. Dupuytren's Contracture. Up to Date online. Accessed Feb, 2018.
4. **Ghazi M. Rayan, MD.** Dupuytren Disease: Anatomy, Pathology, Presentation, and Treatment. *The Journal of Bone and Joint Surgery (American).* 2007;89:189-198. Accessed April 14, 2010.
5. Lawrence C. Hurst, M.D., etc. Injectable Collagenase Clostridium Histolyticum for Dupuytren's Contracture. The New England Journal of Medicine. 2009; Volume 361:968-979
6. Brant WO et al. Peyronie's disease: Diagnosis and Medical Management. UpToDate. Available at www.uptodate.org. Accessed February, 2018
7. Sherer BA el al. 2013-2014 Updates in Peyronie's Disease Management. Curr Urol Rep. 2014 Dec;15(12):459.
8. Nehra A et al. Peyronie's Disease: Treatment algorithm. American Urological Association. Available at https://www.auanet.org/guidelines/guidelines/peyronies-disease-guideline. Accessed November, 2021

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.169 Xiaflex Policy retired, new policy created	1/1/2021	P&T Committee
11/11/2021	P&T Annual Review: Updated criteria for Dupuytren's contracture; Removed trial and failure requirements for Peyroine's disease; added prescriber restriction	3/1/2022	P&T Committee

Next Review Date

11/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with

applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.